Nos. 15-5021 and 15-5022 (consolidated)

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

TAKEDA PHARMACEUTICALS U.S.A., INC., and
ELLIOTT ASSOCIATES, L.P., ELLIOTT INTERNATIONAL, L.P.,
and KNOLLWOOD INVESTMENTS, L.P.,

Plaintiffs-Appellants,

v.

SYLVIA MATHEWS BURWELL, in her official capacity as Secretary,
U.S. Department of Health and Human Services, and
MARGARET HAMBURG, M.D., in her official capacity as Commissioner of
Food and Drugs, Food and Drug Administration,

Defendants-Appellees.

HIKMA PHARMACEUTICALS PLC and
WEST-WARD PHARMACEUTICALS CORP.,

Intervenor-Defendants-Appellees.

On Appeal From The United States District Court For The District Of Columbia
Case Nos. 14-cv-1668 (KBJ) and 14-cv-1850 (KBJ)

APPELLANTS ELLIOTT ASSOCIATES, L.P., ELLIOTT INTERNATIONAL, L.P., AND KNOLLWOOD INVESTMENTS, L.P.'S PETITION FOR REHEARING AND/OR REHEARING *EN BANC*

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GLOSSARY

ANDA	Abbreviated New Drug Application
APA	Administrative Procedure Act
FDA	Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act
NDA	New Drug Application

INTRODUCTION AND SUMMARY

The panel's decision dismissing this appeal as moot conflicts with precedent from the Supreme Court and several courts of appeals regarding the proper application of the Hatch-Waxman Amendments to the Food, Drug, and Cosmetics Act ("FDCA") and the 30-month stay provision. Rehearing is warranted.

This appeal presents important questions regarding whether Section 505(b)(2)(A) of the FDCA and the Food and Drug Administration's ("FDA") implementing regulations require a generic manufacturer, like Hikma, to certify to FDA that its drug will not infringe patents held by innovators, like Takeda, for a brand drug containing the exact same active ingredient indicated for the exact same use. Where such a certification is required, the Hatch-Waxman Amendments create a unique cause of action allowing the innovator to sue the applicant for patent infringement, triggering an *automatic* 30-month stay of FDA's approval of the applicant's drug. 21 U.S.C. § 355(c)(3)(C).

In this case, FDA approved Hikma's application for a drug, Mitigare, without requiring certification, thereby denying Takeda the right to file a Hatch-Waxman lawsuit triggering the 30-month stay. As a result, Takeda brought a distinctly different, *non*-Hatch-Waxman patent-infringement lawsuit—which does *not* trigger the 30-month stay—against Hikma in Delaware (the "Delaware Proceeding"). It also prompted Elliott Associates, L.P., Elliott International, L.P., and

Knollwood Investments, L.P. (together, "Elliott")—all investors in Takeda's brand drug—and Takeda to sue under the APA to vacate FDA's unlawful approval.

After the District Court for the District of Delaware dismissed Takeda's patent-infringement suit against Hikma, the panel dismissed this appeal as moot, citing the provision of the Hatch-Waxman Amendments that terminates the 30-month stay upon entry of a judgment of non-infringement *only* "[i]f the applicant made a certification" to the innovator's patents and the innovator subsequently sued "for infringement of *the patent that is the subject of the certification*." 21 U.S.C. § 355(c)(3)(C) (emphasis added). But here, Hikma never made the required certification and Takeda was precluded from bringing a Hatch-Waxman infringement suit. The panel's unprecedented decision departs from a uniform body of case law distinguishing between *post*-certification patent-infringement cases subject to the limitations of § 355(c)(3)(C), and *non*-certification patent-infringement cases like the Delaware Proceeding to which that provision does not apply.

The panel's conclusion that "Takeda would not receive any stay of FDA's approval" (A3) also conflicts with *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012), which explained that "[f]iling a paragraph IV certification" is "itself an act of infringement" that "gives the brand an immediate right to sue." If the brand does so, FDA may not approve the application "until 30 months pass or the court finds the patent invalid or not infringed." *Id.*

The panel also made two additional holdings that bring its decision even further into conflict with the decisions of other courts. First, it held that a district court's "ent[ry of] judgment reflecting [its] decision" that the innovator's patents are invalid or not infringed (21 U.S.C. § 355(c)(3)(C)(i)(I)) forecloses any "possibility" of a 30-month stay—even if the district court vacates that judgment.[1] Second, it held that its novel interpretation of § 355(c)(3)(C) applies even to a patent *never asserted* in the Delaware Proceeding, contrary to Federal Circuit precedent.

Accordingly, rehearing is warranted because this proceeding involves a question of exceptional importance—indeed, a question on which this Court is now in conflict with decisions of the Supreme Court and several other courts of appeals properly limiting § 355(c)(3)(C) to Hatch-Waxman lawsuits.

BACKGROUND

Statutory Framework. Under the Hatch-Waxman Amendments, a drug company seeking FDA approval for a new drug must use one of three pathways:

First, innovators of novel drug products must file a New Drug Application ("NDA") containing detailed information about the drug's safety, efficacy, and proposed method of use and identifying relevant patent information. 21 U.S.C.

[1] Takeda has moved under Federal Rule of Civil Procedure 59 to modify the judgment and has sought leave to file a second amended complaint. The Delaware district court has not yet ruled on that motion.

§ 355(b)(1)(G). FDA lists this patent information in a publication known as the "Orange Book." *See* 21 C.F.R. § 314.53(e). ***Second***, a generic drug manufacturer seeking to market an exact copy of an innovator's drug can file an Abbreviated New Drug Application, or ANDA. 21 U.S.C. § 355(j).[2] ***Third***, a manufacturer may seek to market a new drug product differing only slightly from an innovator's drug by submitting a type of NDA governed by Section 505(b)(2) of the FDCA. *See* 21 U.S.C. § 355(b)(2); 21 C.F.R. § 314.54(a). These so-called 505(b)(2) applications allow manufacturers to rely on previous investigations conducted by prior applicants and on published studies and literature (rather than solely the 505(b)(2) applicant's studies) to establish the safety and efficacy of the new drug.

In creating the ANDA and 505(b)(2) pathways, Congress also created "an important new mechanism designed to guard against infringement of patents relating to pioneer drugs." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676-77 (1990). Manufacturers using these pathways must provide a certification regarding each of the innovator patents listed in the Orange Book. The certification at issue here is known as a "Paragraph IV" certification: that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug." 21 U.S.C.

[2] An ANDA relies on the innovator's safety and efficacy data by showing that the generic drug "has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Caraco*, 132 S. Ct. at 1676.

§ 355(b)(2)(A)(iv) (505(b)(2) applications); *id.* § 355(j)(2)(vii)(IV) (ANDAs).

A Paragraph IV certification triggers a chain of events that determines when "[FDA] approval of an ANDA or [505(b)(2) application] can be made effective." *Eli Lilly*, 496 U.S. at 677. "It shall be an act of infringement to submit an [ANDA or 505(b)(2)] application" for a drug "the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A). A patent holder then has 45 days after receiving notice of the Paragraph IV certification to bring a specialized action "for infringement of the patent that is the subject of the certification." 21 U.S.C. § 355(c)(3)(C); *id.* § 355(j)(5)(B)(iii). If such an infringement action is brought, any FDA approval is stayed for 30 months from the date the patent holder received notice of the certification. *Id.* § 355(c)(3)(C); *id.* § 355(j)(5)(B)(iii). However, if "the district court" in that pre-launch infringement suit "decides that the patents are invalid or not infringed[,] . . . the approval shall be made effective on . . . the date on which the court enters judgment reflecting the decision." *Id.* § 355(c)(3)(C)(i)(I); *id.* § 355(j)(5)(B)(iii)(I)(aa); *see also Eli Lilly*, 496 U.S. at 677-78.

Hikma's 505(b)(2) Application For Mitigare. In 2009, FDA approved an application by Takeda's predecessor ("Mutual"), for Colcrys®, an oral tablet containing 0.6 mg of colchicine to be used for the treatment of acute gout flares and for the prophylaxis of gout flares. JA34, JA107, JA476-77, JA479, JA503. Mutual obtained patents relating to the use of colchicine for various treatments, includ-

ing four patents listed in the Orange Book as claiming a "[m]ethod of using colchicine for the prophylaxis of gout flares" (the "Colcrys® use patents"). JA515. Hikma first submitted a 505(b)(2) application for a copy of Colcrys® but was rebuffed when FDA agreed with Mutual that any duplicate version of Colcrys® must be submitted as an ANDA, not a 505(b)(2). *See* JA472-73. Hikma then made a miniscule change from a *tablet* to a *capsule* and filed another 505(b)(2) application. *See* JA517. This time, Hikma purported to rely upon studies for an unpatented drug, Col-Probenecid, that has different active ingredients, different concentrations, a different dosage form, and a different indication than Mitigare. Hikma did not certify to the Colcrys® use patents, even though Mitigare's indication mirrors the use listed for those patents in the Orange Book—use of colchicine for prophylaxis of gout. Without requiring patent certification, FDA approved Hikma's application in September 2014, and Hikma launched Mitigare in early 2015.

Ensuing Legal Proceedings. Because FDA did not require Hikma to certify to the Colcrys® use patents, Takeda was denied its right to file a pre-approval Hatch-Waxman patent-infringement suit and to obtain the automatic stay of FDA approval for 30 months contemplated by 21 U.S.C. § 355(c)(3)(C). Takeda was thus relegated to filing a non-Hatch-Waxman patent-infringement suit against Hikma in the District of Delaware, alleging that Hikma was "actively inducing others to directly infringe the claims of" several patents held by Takeda relating to

Colcrys®, including three of the four Colcrys® use patents. First Am. Compl. 20-27, *Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, No. 1:14-cv-01268-SLR (D. Del. filed Sept. 10, 2015).

Independently, Elliott filed suit in the district court below to set aside FDA's unlawful approval of Mitigare. Because "FDA may not approve an application that lacks a required certification" (FDA Br. 5), Elliott argued that Section 505(b)(2)(A) and FDA's implementing regulations required Hikma to certify to the Colcrys® use patents because Hikma sought approval of Mitigare for "an indication that, according to the [Orange Book] . . . , is claimed by a use patent." 21 C.F.R. § 314.50(i)(1)(iii)(B). Takeda also filed its own APA challenge. The district court granted summary judgment for FDA in both cases. JA96.

Elliott and Takeda appealed to this Court. After full briefing and oral argument on the merits, Hikma notified the panel that the district court in the Delaware Proceeding had dismissed Takeda's non-Hatch-Waxman suit. On Hikma's motion, the panel dismissed this appeal as moot, reasoning that "even if we were to hold that Hikma should have certified to Takeda's patents, that decision would at most entitle Takeda to a stay of FDA's approval of Mitigare pending a district court decision on the patent infringement suit." A3. Citing 21 U.S.C. § 355(c)(3)(C)(i)(I), which specifies when the 30-month stay in a *Hatch-Waxman* case terminates, the panel held that "there has already been a district court judgment on the patent in-

fringement suit, so Takeda would not receive any stay of FDA's approval of Mitigare." A3. Because the Delaware decision left Takeda "[w]ithout the possibility of such a stay," the panel reasoned, "forcing Hikma to reapply [with the proper certification] would provide no meaningful redress to Takeda and Elliott." *Id.* The panel also rejected as "unavailing" Elliott's argument that, even if § 355(c)(3)(C) applied to the Delaware Proceeding, a stay is still available for the Colcrys® use patent on which Takeda did not sue. *Id.*

ARGUMENT

Numerous courts, including this one, have recognized that 21 U.S.C. § 355(c)(3)(C) and the parallel provision for ANDAs, *id.* § 355(j)(5)(B)(iii), control the availability of a stay of FDA approval *only* where "the applicant made a certification" to a patent and the patent holder "brought [an action] for infringement of the patent that is the subject of the certification" (*id.* § 355(c)(3)(C))—in other words, only in Hatch-Waxman litigation brought under 35 U.S.C. § 271(e)(2). The panel's conclusion that "*any* district court judgment concluding that the patent is not infringed" suffices to render a stay unavailable (A2 (emphasis added)) is contrary to this uniform precedent.

In addition, the panel—without full briefing or argument on the issue—delivered the first decision of which Elliott is aware to hold that a district court's entry of a judgment of non-infringement *irrevocably* terminates the stay of FDA

approval under § 355(c)(3)(C), even if the district court revisits the judgment. *See* A3. That conclusion is contrary to both the statutory text and the settled rule that Rule 59(e) provides a plaintiff with a "window in which to seek to reopen the judgment and amend the complaint." *Fletcher-Harlee Corp. v. Pote Concrete Contractors, Inc.*, 482 F.3d 247, 253 (3d Cir. 2007).

Finally, the panel's conclusion that Takeda would never be entitled to a future stay, even if Hikma were required to certify to the patent that the Delaware court "did not adjudicate" because it was not at issue (A3), is contrary to the Federal Circuit's application of preclusion principles to patents. *See*, *e.g.*, *Abbey v. Mercedes Benz of N. Am., Inc.*, 138 F. App'x 304, 307 (Fed. Cir. 2005) ("when patents are not included in a suit, they are not before a court, and . . . causes of action based on patents that are not included in a suit are ordinarily not . . . precluded . . . by judgments that pertain to other patents").

Given the panel's novel construction on these points and the conflicts created with other circuits, parties will freely cite the panel's opinion in future cases notwithstanding the fact that it is unpublished. *See* Fed. R. App. P. 32.1. Rehearing is necessary to resolve these conflicts and prevent the panel's decision from introducing costly uncertainty into Hatch-Waxman litigation.

I. THE PANEL'S NOVEL CONSTRUCTION OF 21 U.S.C. § 355(c)(3)(C) TO APPLY TO THE DELAWARE PROCEEDING CONFLICTS WITH A UNIFORM BODY OF DECISIONS

The panel construed 21 U.S.C. § 355(c)(3)(C) to mean that "*any* district court judgment concluding that the patent is not infringed"—including, as here, a judgment in a *non*-Hatch-Waxman patent lawsuit—would cut off any 30-month stay of FDA approval for a drug for which a manufacturer submitted a 505(b)(2) application. A2 (emphasis added). That unprecedented construction departs from the statute's plain text, which states that the provision applies *only* "[i]f the applicant made a [Paragraph IV] certification" and the patentee brought "an action . . . for infringement of *the patent that is the subject of the certification*." 21 U.S.C. § 355(c)(3)(C) (emphasis added). Patent-infringement litigation brought under Hatch-Waxman after such a certification is unique. "The patent statute treats such a filing as itself an act of infringement, which gives the brand an immediate right to sue" (*Caraco*, 132 S. Ct. at 1677), and only that specific class of litigation automatically stays FDA approval of the applicant's drug. *See Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1037 (9th Cir. 2009) (only a suit brought "under Hatch-Waxman" triggers the "automatic stay"). It follows that the only "judgment" that can terminate a 30-month stay is one entered in a Hatch-Waxman suit brought under 35 U.S.C. § 271(e)(2). 21 U.S.C. § 355(c)(3)(C)(i)(I) explains that if the court *in a Hatch-Waxman suit* "decides that the patent is invalid

or not infringed," the automatic stay is no longer needed and ends when "the court enters judgment reflecting the decision."

Here, there was no Hatch-Waxman suit because FDA failed to require the requisite patent certification. Hikma *never* certified with respect to Takeda's patents (and no stay issued), forcing Takeda to bring a *non*-Hatch-Waxman infringement lawsuit against Hikma in Delaware. Thus, the decision in the Delaware Proceeding has no bearing on the 30-month stay or the effective date of any FDA approval if Elliott prevails in this case and Hikma is required to submit a new application with the required patent certifications. The panel's construction of § 355(c)(3)(C) is contrary to the body of authority making clear that the filing of a Hatch-Waxman lawsuit "automatically" triggers a 30-month stay. *E.g.*, *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1343, 1344 (Fed. Cir. 2007). If Hikma is required to certify to the Colcrys patents, there *will* be a 30-month stay of approval regardless of what has happened (or happens) in the Delaware Proceeding. Nor can the Delaware judgment serve as a litmus test for the likelihood that Takeda will succeed or fail in a hypothetical Hatch-Waxman suit (let alone receive the automatic stay), because the act of infringement in a Hatch-Waxman suit is the filing of the 505(b)(2) or ANDA application (35 U.S.C. § 271(e)(2)(A)), not the very different facts at issue in the Delaware Proceeding.

Until the panel's ruling, *every* federal court (including this Court) to apply

§ 355(c)(3)(C) and its companion provision for ANDAs, § 355(j)(5)(B)(iii), properly applied them exclusively to judgments entered in Hatch-Waxman patent-infringement litigation. *E.g.*, *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004) ("If the patent holder sues [under Hatch-Waxman after a certification], the FDA must wait thirty months from the notice date before approving the ANDA unless the applicant wins the suit sooner . . . .").[3] Elliott is aware of no prior case in which a court applied the Hatch-Waxman entry-of-judgment provision to terminate (or preempt) a stay based on a judgment in a non-Hatch-Waxman case. The panel's unprecedented application of that cutoff departs from this uniform precedent and, despite being unpublished, will be cited to lend this Court's imprimatur to further distortions of the Hatch-Waxman Amendments. This Court should correct the panel's misapplication of § 355(c)(3)(C); at a minimum, the Court should consider the question with the benefit of full briefing and argument.

II. THE PANEL'S CONSTRUCTION OF 21 U.S.C. § 355(c)(3)(C) TO ELIMINATE ANY POSSIBILITY OF A 30-MONTH STAY IS UNPRECEDENTED

In addition to holding that § 355(c)(3)(C) applies in this case (it does not), the panel further construed that provision to terminate any "possibility" of a 30-

[3] *See also Caraco*, 132 S. Ct. at 1677; *Kaiser Found. Health Plan, Inc.*, 552 F.3d at 1037; *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 901 (6th Cir. 2003); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1297 (11th Cir. 2003); *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 778 (Fed. Cir. 2002).

month stay, even if the district court revisits its judgment. Although the Delaware judgment is presently the subject of a motion to reopen, the panel concluded that the judgment nonetheless left Takeda "[w]ithout the possibility of [a future] stay." A3. Thus, under the panel's construction of § 355(c)(3)(C), a decision by the Delaware court to reopen the judgment would not restore Takeda's right to a 30-month automatic stay if FDA's approval of Mitigare were vacated and Hikma submitted a new application with the required certifications. That construction, too, is unprecedented. At a minimum, the Court should order briefing and argument on this important question of first impression.

21 U.S.C. § 355(c)(3)(C)(i)(I) states only that FDA approval shall be effective if the district court in Hatch-Waxman proceedings has "enter[ed] judgment reflecting [its] decision" "that the patent is invalid or not infringed." It does not purport to abrogate the default rule that a party has a "window in which to seek to reopen the judgment." *Fletcher-Harlee Corp.*, 482 F.3d at 253. Nor does § 355(c)(3)(C)(i)(I) purport to alter the bedrock principle that "[a] vacated judgment has no effect." *Fort Knox Music Inc. v. Baptiste*, 257 F.3d 108, 110 (2d Cir. 2001); *accord United States v. Munsingwear, Inc.*, 340 U.S. 36, 41 (1950). If the Delaware district court grants Takeda's Rule 59(e) motion, then manifestly there is no "judgment" of non-infringement to foreclose the availability of a 30-month stay if and when Hikma makes the required patent certifications.

Moreover, the panel's inflexible construction would make little sense under the Hatch-Waxman statutory scheme. The purpose of the 30-month stay is "to create an adequate window of time during which to litigate the question of whether [an applicant's drug] will infringe the patented product, without actually having to introduce [the drug] to the market." *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001). The Delaware district court dismissed Takeda's lawsuit before it had the benefit of Takeda's new allegations; and by hastily applying § 355(c)(3)(C)(i)(I) even before Takeda's pending Rule 59(e) motion was resolved, the panel short-circuited the Hatch-Waxman process.

III. THE PANEL IMPROPERLY DECIDED THAT PATENT NO. 7,820,681—WHICH THE DELAWARE COURT NEVER ADJUDICATED—CANNOT ITSELF SUPPORT A STAY

Finally, the panel held that Takeda could not obtain a stay if Hikma were required to certify to the Colcrys® use patent No. 7,820,681 (the "'681 patent"), even though the District of Delaware undisputedly "did not adjudicate" that patent. A3. There is no tenable basis for that holding.

First, the panel may have concluded that Mitigare does not infringe that patent. But questions of patent infringement are for the Federal Circuit's exclusive jurisdiction. *See* 28 U.S.C. § 1295(a)(1). Even if this Court had jurisdiction to adjudicate that issue, the *Chenery* doctrine would forbid it in this case, as FDA never reached any conclusion about whether Hikma had infringed or would infringe

Takeda's patents. *See SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943).

Second, the panel may have concluded that even though the Delaware court "did not purport to adjudicate" the '681 patent (A3), its conclusions with respect to the other patents resolve whether Mitigare infringes the '681 patent. That conclusion is also unjustified—no recognized principle of preclusion can extend the Delaware court's decision to the '681 patent, which "raises an independent and distinct cause of action." *Kearns v. Gen. Motors Corp.*, 94 F.3d 1553, 1555 (Fed. Cir. 1996); *see id.* at 1557 ("[T]he dismissal of the [separate suit] did not impose the bar of res judicata upon patents that had not been included in [that] suit, were not before [that] court, and were not part of [that] judgment.").[4] To the extent the panel held otherwise, it brought this Court's law into conflict with Federal Circuit decisions. Takeda has not forfeited its entitlement to bring a Hatch-Waxman suit within forty-five days of receiving an appropriate certification, triggering the automatic stay, by not asserting the '681 patent in the Delaware Proceeding.

CONCLUSION

This Court should grant rehearing or, in the alternative, rehearing *en banc*.

Respectfully submitted,

[4] *See also Abbey*, 138 F. App'x at 307 ("*Kearns* provides that normally when patents are not included in a suit, they are not before a court, and . . . causes of action based on patents that are not included in a suit are ordinarily not captured, and therefore precluded, by judgments that pertain to other patents.").

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Dated: August 29, 2016.

CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of August, 2016, I caused the foregoing Appellants Elliott Associates, L.P., Elliott International, L.P., And Knollwood Investments, L.P.'s Petition For Rehearing And/Or Rehearing *En Banc* to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit using the appellate CM/ECF system. Service was accomplished on the following parties via the Court's CM/ECF system:

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ADDENDUM

ADDENDUM CONTENTS

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 15-5021 **September Term, 2015**

FILED ON: JULY 15, 2016

TAKEDA PHARMACEUTICALS U.S.A., INC.,
APPELLANT

ELLIOTT ASSOCIATES, L.P., ET AL.,
APPELLEES

v.

SYLVIA MATHEWS BURWELL, IN HER OFFICIAL CAPACITY AS SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,
APPELLEES

Consolidated with 15-5022

Appeals from the United States District Court
for the District of Columbia
(No. 1:14-cv-01668)
(No. 1:14-cv-01850)

Before: KAVANAUGH and WILKINS, *Circuit Judges*, and SILBERMAN, *Senior Circuit Judge*.

JUDGMENT

This appeal was considered on the record from the United States District Court for the District of Columbia and on the briefs and oral arguments of the parties. The Court has afforded the issues full consideration and has determined that they do not warrant a published opinion. *See* D.C. Cir. R. 36(d). It is

ORDERED and **ADJUDGED** that the portion of the appeal seeking review of FDA's decision to approve Mitigare without Hikma's certifying to the Colcrys patents be **DISMISSED AS MOOT** and that this portion of the judgment of the District Court be **VACATED**. It is

FURTHER ORDERED and **ADJUDGED** that the portion of the judgment of the District Court regarding Takeda's challenge to FDA's approval of the Mitigare label be **AFFIRMED**.

In 2009, the Food and Drug Administration approved Colcrys, a drug for the prevention and treatment of acute gout flares. Five years later, FDA approved a new drug – Mitigare – also for the prevention of gout flares.

When an applicant seeks FDA approval for a new drug under the Food, Drug, and Cosmetic Act, the applicant must generally certify to any patents "relied upon by the applicant for approval of the application." 21 U.S.C. § 355(b)(2). One such certification is called a Paragraph IV certification. A Paragraph IV certification is generally used when an applicant seeks to market a new drug that is essentially identical to a previously approved drug and the applicant claims that the patent for the previously approved drug "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* § 355(b)(2)(A)(iv). As relevant here, an applicant filing a Paragraph IV certification must also notify the owner of the patents for the previously approved drug. *Id.* § 355(b)(3).

Once the applicant has made the Paragraph IV certification, FDA's "approval shall be made effective immediately." *Id.* § 355(c)(3)(C). If, however, the patent owner brings an infringement action against the applicant within 45 days of receiving notice, then FDA must stay its approval for up to 30 months or until specified events happen in the patent litigation. *See id.* Of relevance here, if a district court decides "that the patent is invalid or not infringed," then FDA "approval shall be made effective on the date on which the court enters judgment reflecting the decision." *Id.* § 355(c)(3)(C)(i)(I). For present purposes, the most important point is this: If a patent infringement action is brought, then FDA approval of the application must be made effective on the date of any district court judgment concluding that the patent is not infringed.

When Hikma Pharmaceuticals applied for FDA approval of Mitigare, Hikma did not certify to the Colcrys patents. As a result, Colcrys's manufacturer – Takeda Pharmaceuticals – was not able to obtain a 30-month stay of FDA's approval of Mitigare. When Takeda discovered that FDA had approved Mitigare, Takeda sued Hikma for patent infringement in the U.S. District Court for the District of Delaware. The District Court of Delaware recently found no infringement of Takeda's patents and dismissed Takeda's infringement suit. *See Takeda Pharmaceuticals U.S.A., Inc. v. West-Ward Pharmaceutical Corp.*, Civ. No. 14-1268-SLR (May 18, 2016).

Meanwhile, Takeda also sued FDA in the U.S. District Court for the District of Columbia, alleging that the agency had acted arbitrarily and capriciously for purposes of the Administrative Procedure Act. The D.C. District Court consolidated Takeda's suit with a similar suit brought by Elliott Associates, a hedge fund with rights to a percentage of royalties from the domestic sale of Colcrys. First, Takeda and Elliott claimed that Hikma should have certified to the Colcrys patents under Paragraph IV and that FDA should not have approved Hikma's application without that certification. Second, Takeda also alleged that FDA had impermissibly departed from agency precedent in approving the Mitigare label.

We conclude that the first issue – whether Hikma should have certified to the Colcrys patents under Paragraph IV – is moot because the underlying issue of infringement has already been resolved in Hikma's favor by the District Court of Delaware. "A case is moot if events have so transpired that the decision will neither presently affect the parties' rights nor have a more-than-speculative chance

of affecting them in the future." *Pharmachemie B.V. v. Barr Laboratories, Inc.*, 276 F.3d 627, 631 (D.C. Cir. 2002) (internal quotation marks omitted). Here, even if we were to hold that Hikma should have certified to Takeda's patents, that decision would at most entitle Takeda to a stay of FDA's approval of Mitigare pending a district court decision on the patent infringement suit. But there has already been a district court judgment on the patent infringement suit, so Takeda would not receive any stay of FDA's approval of Mitigare. Without the possibility of such a stay, Takeda's and Elliott's claims about Hikma's failure to certify to the Colcrys patents are academic and moot. *Cf. id.*

Takeda and Elliott offer three other primary reasons why the certification issue is not moot. *First*, Takeda and Elliott argue that Hikma should be made to go through the motions of re-applying to FDA for approval of Mitigare. But given the District Court of Delaware's decision, forcing Hikma to reapply would provide no meaningful redress to Takeda and Elliott. *Second*, Takeda also refers to the bond it posted in the District Court of Delaware. But that is an issue for the District Court of Delaware to resolve, as explained more fully below. *Third*, Elliott (but importantly not Takeda) argues that the District Court of Delaware did not purport to adjudicate all of the patents that Hikma was allegedly obligated to certify to. So, Elliott contends, Takeda could still sue Hikma for infringement and obtain the 30-month stay. But the reason that the District Court of Delaware did not adjudicate all of the patents is because Takeda did not sue Hikma based on all of the patents. That no doubt is why Takeda has not joined Elliott in advancing this argument as a basis for rejecting mootness. In short, Elliott's argument is unavailing.

We have carefully considered all of the arguments about mootness. We conclude that Takeda and Elliott's challenge to FDA's decision to approve Mitigare without Hikma's certifying to the Colcrys patents is moot. To state the obvious, if FDA ever concludes that Mitigare is no longer safe and effective, FDA has an array of statutory and regulatory tools to pull it off the market. *See* 21 U.S.C. § 355(e). But the dispute over whether Hikma should have certified to the Colcrys patents under Paragraph IV is moot.

In so ruling, we emphasize that our decision should have no impact on the District Court of Delaware's ruling on the Rule 65 bond issue. In particular, the District Court of Delaware may independently decide whether Hikma should have certified under Paragraph IV to the Colcrys patents, as well as whether and how the answer to that question should affect the District Court's resolution of the Rule 65 bond issue. In that regard, we note that the District Court of Delaware's initial ruling on the TRO stated that "Hikma has effectively side-stepped" the Paragraph IV certification process "in an effort to get its generic product to market without appropriate legal underpinnings." Memorandum Order at 6, *Takeda Pharmaceuticals U.S.A., Inc. v. West-Ward Pharmaceutical Corp.*, No. 14-1268 (D. Del. Oct. 9, 2014). The District Court of Delaware factored that point into its analysis of the balance of hardships and the public interest, and the court may do so again if it believes doing so would be relevant to resolution of the Rule 65 bond issue.

Apart from its claim about Hikma's failure to certify, Takeda also argues that the Mitigare label impermissibly omits critical safety information. That claim is not moot, but we disagree on the merits with Takeda. When FDA makes scientific judgments, this Court owes the agency the "most deferential" review. *Baltimore Gas & Electric Co. v. Natural Resources Defense Council,*

Inc., 462 U.S. 87, 103 (1983). Here, FDA affirmatively chose to depart from some past statements it had made about the labeling of products for the prevention and treatment of acute gout flares. As the record makes clear, the agency "employed its scientific expertise to reach" each of those decisions. *Takeda Pharmaceuticals, U.S.A., Inc. v. Burwell*, 78 F. Supp. 3d. 65, 107 (D.D.C. 2015). FDA then adequately explained those decisions through "various memos detailing its considerations and conclusions." *Id.* As the District Court concluded, "Takeda has not established that the APA requires anything more." *Id.*

In sum, we dismiss as moot the portion of the appeal seeking review of FDA's decision to approve Mitigare without Hikma's certifying to the Colcrys patents, and we affirm the judgment of the District Court with respect to Takeda's challenge to FDA's approval of the Mitigare label.

Pursuant to D.C. Circuit Rule 36, this disposition will not be published. The Clerk is directed to withhold issuance of the mandate herein until seven days after resolution of any timely petition for rehearing or rehearing en banc. *See* Fed. R. App. P. 41(b); D.C. Cir. R. 41.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Ken Meadows
Deputy Clerk

CERTIFICATE AS TO PARTIES AND AMICI CURIAE

Pursuant to D.C. Circuit Rules 28(a)(1) and 35(c), Plaintiffs-Appellants state as follows:

The parties in this Court's Case Nos. 15-5021 and 15-5022 are Plaintiff-Appellant Takeda Pharmaceuticals U.S.A., Inc. ("Takeda"); Plaintiffs-Appellants Elliott Associates, L.P., Elliott International, L.P., and Knollwood Investments, L.P. (together, the "Elliott"); Defendant-Appellee Sylvia Mathews Burwell, in her official capacity as Secretary, United States Department of Health and Human Services; Defendant-Appellee Margaret Hamburg, M.D., in her official capacity as Commissioner of Food and Drugs, Food and Drug Administration ("FDA"); Intervenors-Defendants-Appellees Hikma Pharmaceuticals PLC and West-Ward Pharmaceuticals Corp. (together, "Hikma"); Pharmaceutical Research and Manufacturers of America (PhRMA), as amicus curiae in support of Appellants; and Generic Pharmaceutical Association, as amicus curiae in support of Appellees and Intervenors-Defendants-Appellees.

/s/ Michael A. Sitzman
Michael A. Sitzman

RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rules 26.1 and 35(c), the Elliott Appellants state as follows:

Elliott Associates, L.P. is a Delaware limited partnership that has no publicly held parent, and no publicly held entity controls or owns 10% or more of Elliott Associates, L.P.

Elliott International, L.P. is a Cayman Islands limited partnership that has no publicly held parent, and no publicly held entity controls or owns 10% or more of Elliott International, L.P.

Knollwood Investments, L.P. is a Delaware limited partnership that has no publicly held parent, and no publicly held entity controls or owns 10% or more of Knollwood Investments, L.P.

The Elliott Appellants are the record-holder and economic beneficiaries of a contingent value right to receive royalties from the sale of Colcrys® in the United States so long as the Colcrys® use patents remain in force.

/s/ Michael A. Sitzman
Michael A. Sitzman